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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/887,505	07/02/1997	ROBERT L. KILKUSKIE	HYZ-040CIP	1117

7590 10/20/2005

HALE AND DORR  
60 STATE STREET  
BOSTON, MA 02109

EXAMINER

MARTINELL, JAMES

ART UNIT PAPER NUMBER

1634

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/887,505

Applicant(s)

KILKUSKIE ET AL.

Examiner

James Martinell

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 August 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31 and 42-45 is/are pending in the application.
- 4a) Of the above claim(s) 7,23,24,26,29,31 and 46 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21 and 42 is/are allowed.
- 6) ☒ Claim(s) 1-6,8-20,22,25,27,28,30 and 43-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 July 1997 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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The amendments for pages 29-30 have not been entered because the amendment is not in compliance with 37 CFR § 1.121(b).

The amendments to claims 9 and 14 are improper in that "one" has been changed to "on" in each of the claims without a signaling of a change. Each of the claims should be cancelled and re-submitted as new claims.

Applicant's election with traverse of the requirement for restriction in the reply filed on August 19, 2005 is acknowledged. The traversal is on the ground(s) that at least ten and up to twenty separate sequences should be searched. Applicants cite MPEP § 803.04 which states that up to ten independent and distinct nucleotide sequences may be searched in a single application. This is not found persuasive because the statement in the MPEP does not create a right to the examination of ten independent and distinct nucleotide sequences in a single application. USPTO sequence searching and examination resources do not permit the searching of more than two independent and distinct sequences in the instant application. Applicants should note that two sequences is within the range of one to ten sequences. Applicants give no reason why the USPTO should consider searching twenty sequences in the instant application and why the searching and examination of twenty nucleotide sequences would not be a burden to search. In addition, applicants then attempt to elect ten combinations of sequences for claims 42-45, declaring merely that it would not be a burden for the USPTO to search the ten combinations. This request is denied for reasons given above. Since no prior art was found for SEQ ID NO: 28, all of the combinations containing SEQ ID NO: 28 are free of the prior art. Only SEQ ID NO: 28 was searched for combination claims 42-45.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7, 23, 24, 26, 29, 31, and 46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 19, 2005.

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6, 8-20, 22, 25, 27, 28, 30, 43, and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite.

- (a) The recitation of "synthetic oligonucleotide" (claims 1, 2, 4, 5, 8, and 43) is vague and indefinite because the instant application does not distinguish between synthetic oligonucleotides and non-synthetic oligonucleotides. Applicants' arguments (response filed August 19, 2005, page 16), Lockhart et al (Nature Biotechnology 14: 1675 (1996)), and Halpern et al (abstract of Cellular Immunology 167 (1), 72 (1996)) are not persuasive. The instant application at pages 10-11 does not define the term, but merely states a class of compounds that are to be considered included by the use of the term. Neither of the references cited defines the term. Mere use of a term is not a substitute for a definition.

Claims 2-6, 8-20, 25, 27, 28, 30, 43, and 45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed April 29, 2005, paragraph bridging pages 4-5). Applicants' arguments response filed August 19, 2005, pages 17-18) are not convincing. The instant application does not contain an adequate written description of all of the functional regions listed in the claims. A functional description of the nucleic acids is not sufficient to meet the written description requirement (*e.g.*, see *Regents of the University of California v. Eli Lilly*, 43 USPQ2d 1398 (Fed. Cir. 1997)).

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Claims 2-6, 8-20, 25, 27, 28, 30, 43, and 45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 38, does not reasonably provide enablement for all of the claimed combinations. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for reasons already of record (*e.g.*, Office action mailed April 29, 2005, page 5, first full paragraph). Applicants' arguments (response filed August 19, 2005, pages 18-18) are not convincing. Since the written description of the claimed invention is inadequate (see the previous rejection), one of skill in the art cannot make and use the full scope of the claimed invention.

Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The substitution of "sequence" for "strand" is new matter. The sense of the claim before the amendment is that the triplex forming nucleic acid is not covalently bound to the oligonucleotide whereas the sense of the claim as amended is that the triplex forming sequence is covalently bound to the oligonucleotide.

Claims 2, 6, 8-12, 22, and 45 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Anderson et al (WO 94/05813 (March 17, 1994)). SEQ ID NO: 38 of Anderson et al comprises SEQ ID NO: 38 of the instant application and thus meets the claims. Anderson et al suggest using the oligonucleotides as therapeutic agents (*e.g.*, see abstract) and further suggest using modified forms of the oligonucleotides (*e.g.*, see page 8) to increase stability.

Claims 21 and 42 are allowable over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (571) 272-0719.

The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to [james.martinell@uspto.gov](mailto:james.martinell@uspto.gov). Since

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e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745.


**OFFICIAL FAX NUMBER**

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Any Official Communication to the USPTO should be faxed to this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
**James Martinell, Ph.D.**  
**Primary Examiner**  
**Art Unit 1634**

10/17/05